US Environmental Protection Agency
Office of Pesticide Programs

Office of Pesticide Programs
Microbiology Laboratory
Environmental Science Center, Ft. Meade, MD

Standard Operating Procedure for
Preparation and Review of Product Performance Reports

SOP Number: ADM-01-06

Date Revised: 04-19-17

SOP Number	ADM-01-06
Title	Preparation and Review of Product Performance Reports
Scope	This protocol describes the procedures for the preparation and review of performance reports for disinfectant products tested for efficacy against one or more microorganisms.
Application	This SOP is applicable for preparation of all performance reports generated by the Microbiology Laboratory Branch (MLB).

	Approval Date
SOP Developer:	_____ Print Name: _____
SOP Reviewer	_____ Print Name: _____
Quality Assurance Unit	_____ Print Name: _____
Branch Chief	_____ Print Name: _____

Date SOP issued:	
Controlled copy number:	
Date SOP withdrawn:	

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1. Definitions	Additional abbreviations/definitions are provided in the text. 1. Performance Report = A report documenting the outcome of a product efficacy evaluation as tested with a specific method. The performance report contains information referred to in Section 12.1. 2. Quality Assurance (QA) Statement = A statement issued by the Quality Assurance Officer (QAO) of the Microbiology Laboratory Branch that identifies the quality assurance audit trail and review of the report.
2. Health and Safety	Not applicable
3. Personnel Qualifications and Training	Refer to SOP ADM-04, OPP Microbiology Laboratory Training.
4. Instrument Calibration	Not applicable
5. Sample Handling and Storage	Not applicable
6. Quality Control	1. The OPP Microbiology Laboratory conforms to 40 CFR Part 160, Good Laboratory Practice (GLP) Standards. Appropriate quality control measures are integrated into each SOP. 2. Studies are tracked in the Master Schedule which is maintained electronically and archived as per SOP QA-04, Master Schedule Preparation.
7. Interferences	1. Incomplete paperwork and documentation can impede the report process and may further impact regulatory and enforcement actions.
8. Non-conforming Data	1. Any nonconformance will be documented and appropriate corrective action(s) will be implemented. Procedures will be consistent with SOP ADM-07, Non-Conformance Reports.
9. Data Management	1. Data will be archived consistent with SOP ADM-03, Records and Archives. 2. Completed reports, original test data sheets, and original study protocols and attachments are archived in file cabinets in room D217. Only authorized personnel have access to D217.
10. Cautions	None
11. Special Apparatus and	None

Materials	
12. Procedure and Analysis	1. A performance report consists of information associated with testing of a product and may include documents such as the study protocol, data sheets, labels, chain of custody (COC) forms, as well as documents required under Good Laboratory Practice Standards such as the GLP Statement and Quality Assurance audit information. The performance report and Biological Report of Analysis form are sent along with a transmittal memo, which summarizes the testing history and is signed by the Branch Chief. 2. Compile and finalize the performance report within 14 business days after all data collection is completed.
12.1 Contents and Format of a Typical Performance Report	Refer to Attachment A for general report format. The performance report is assembled sequentially and consists of, but is not limited to, the following: a. Quality Assurance Unit Statement b. Title Page c. GLP Statement (original signatures) d. Study Protocol and Attachments e. Test Coordinator and Analyst Signature Page (original signatures) f. Data Summary Sheets g. Photocopies of Test Data Sheets (e.g., Test Information Sheet, Results Sheet, Confirmation Sheet, Carrier Count Data sheet and Spreadsheet, Vitek printouts and Test Sheets related to Neutralization Confirmation Assays [when applicable]). h. Photocopies of the Chain of Custody documentation i. Photocopies or photographs of product label on sample container. j. Accompanying the Performance Report is (are) the completed Biological Report(s) of Analysis (BRA) (EPA Form 8510-14).
12.2 Preparation of the Report	a. Assemble the draft report and associated BRA, check it for completeness, and submit to another analyst for peer review. b. Complete a Report Preparation and Quality Control Checklist (see section 14). c. Prepare a draft transmittal memo. d. Once the peer review is complete, submit the draft report to the Study Director or designee who reviews the draft report for errors and

	completeness. e. Incorporate any suggested corrections/changes made by the study director. f. Alternatively, if there are only minor comments, the study director may submit the draft report directly to the Quality Assurance Unit (QAU).
12.3 Quality Assurance Unit Review of a Draft report	a. After completion of the draft report and all subsequent corrections/changes, submit the report to the QAU. b. The QAU reviews the draft report for completeness and determines whether additional revisions/corrections are necessary. c. If errors are noted by the QAU, the QAU either submits a memo outlining the revisions/corrections necessary for the report or makes notations in the draft report and returns it to the lead analyst. d. The lead analyst ensures all required revisions/corrections are completed by the appropriate analyst(s) and submits the final report and signed Biological Report of Analysis (see section 14) to the QAU for final review. Once reviewed by QAU, the lead analyst page stamps the final report. e. The Quality Assurance Officer (QAO) verifies that all corrections or required revisions have been made and issues the QA statement. f. The lead analyst submits the original page stamped report, now known as the final performance report, and one bound copy along with the signed BRA and a draft transmittal memo to the branch chief for signature. g. The branch chief reviews the final performance report and adds signatures and date to the BRA(s). h. The final performance report with original signatures and signed BRA (original signatures) along with a transmittal memo are sent by the branch chief or designee. i. The QAU sends a “Record of Customer Feedback” form (see SOP ADM-08) to solicit feedback on the quality of the laboratory services. j. Scan the transmittal memo, BRA and full report and store electronically. k. One copy of the final report and BRA(s), and original test data sheets, and original study protocols and attachments are archived.

13. Data Analysis/ Calculations	1. None
14. Forms and Data Sheets	1. Attachment A: Report Format: Hospital/General Disinfectant Claims. 2. Test sheets are stored separately from the SOP under the following file names: Report Preparation and Quality Control Checklist ADM-01-06_F1.xlsx Biological Report of Analysis (EPA HQ Form 8510-14) ADM-01-06_F2.xlsx
15. References	1. None

Attachment A

General Guidance
Report Format – Hospital/General Disinfectant Claims

Develop a report as described below for ALL product tests (passing and failing). Please put the documents in the order noted on this list. The BRA and draft transmittal are independent of the body of the report but should be submitted with the report. Please use the "Report Preparation and Quality Control Checklist" as a guide. A report may have additional components depending on the method and the outcome of the test.

Front section: **(no tab required)**
Title Page (Not numbered)
QA Statement (Not numbered)
GLP Statement
Study Protocol
Test Parameters (signed by AD)
Analyst Signature Page (for the study)

For each organism – tab separately (label the tab by organism)
Data Summary Sheet
Test Information Sheet
Test Results Sheet
Confirmation Sheet
Vitek Printouts
Carrier Count Data Sheet
Carrier Count Spreadsheet
Neutralization Results Sheet (if conducted)

Chain of Custody Documentation (label tab as "Chain of Custody")
Shipping and receiving record (optional: package receiving log)
History of Official Sample
Laboratory COC form
Seal Log
Correspondence from the company
Label copies

In addition, the following documentation should be submitted for QA review in a separate folder. Once the report has been reviewed the documentation noted below can be placed under a separate tab in the lab copy only of the report as "Supporting Documentation".

Organism tracking log
Time Recording Sheets (carrier transfer, carrier inoculation)
Media sterility and performance summary sheet
Gram Stain Worksheet (if used)
Serial dilution/plating form
Equipment form
Any unique information specific to the product (prep forms for unusual neutralizers, emails about soil ingredients etc.)